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JUN 29 2012

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Official Contact: Izhak Fabian - CEO

Proprietary or Trade Name: ClearPath Tubing

Common/Usual Name: Irrigation tube

Classification Name/Code: **OCX** – endoscopic irrigation / suction system
Class - 2
CFR 876.1500

Device: ClearPath Tubing

Predicate Devices: K092429 - Byrne Medical – Endogator
K091305 – EasyGlide – ClearPath
K103239 – US Endoscopy – Velocity Irrigation system

Device Description:
The ClearPath Tubing is intended to provide irrigation via irrigation fluids, such as water, during gastrointestinal endoscopic procedures when used in conjunction with the ClearPath irrigation system components (ClearPath Upper GI, ClearPath Lower GI, and ClearPath Irrigator). The ClearPath Tubing is single use, disposable.

The ClearPath irrigation system is designed to improve procedure reliability by improving visualization during endoscopic procedures by performing a colon or stomach wash.

The ClearPath Tubing is used to connect the irrigation fluid source (i.e. water bottle), via the peristaltic pump, to the cleaning device of the ClearPath product family (ClearPath Lower GI, K091305 and K113050, ClearPath Upper GI, K093779 and K113166, and ClearPath Irrigator, K101094). Note that only the ClearPath accessories are to be used with the ClearPath Tubing.

Indications for Use:
The ClearPath Tubing is intended to provide irrigation via irrigation fluids, such as water, during gastrointestinal endoscopic procedures when used in conjunction with the ClearPath irrigation system components.

Patient population:
Individuals undergoing procedures endoscopic procedures.

Environment of Use:
Hospitals, clinics, and doctors' offices.

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Performance testing:
Testing was performed to demonstrate that the ClearPath Tubing functions as intended. The testing included:

- leak detection,
- tubing does not deteriorate,
- no visible degradation

Based on test results it was concluded that the ClearPath Tubing functions safely and effectively for its intended use in conjunction with the ClearPath system components.

Summary of substantial equivalence:
We demonstrate that the ClearPath Tubing is equivalent to the predicates in design and performance characteristics:

The ClearPath Tubing is viewed as substantially equivalent to the predicate devices:

- **Indications** –intended to provide irrigation via irrigation fluids, such as water, during gastrointestinal endoscopic procedures and single use, disposable.
  - Identical to Byrne Medical Endogator tubing K092429 and US Endoscopy Velocity system K103239

- **Technology** – Simple tubing used with a peristaltic pump
  - Identical technology used in predicates EasyGlide ClearPath K091305 and EasyGlide ClearPath K103239, in compatibility to a peristaltic pump and use of a check valve to prevent back flow.

- **Environment of use** –
  - Identical to all predicates Identical to Byrne Medical Endogator tubing K092429 and US Endoscopy Velocity system K103239

- **Materials** –
  - Identical to ClearPath K091305 or tested per ISO 10993

Difference – there are no substantial differences or new features in the proposed device compared to the predicates which raises any new safety or efficacy issues.

	Proposed device	Predicate devices		
510k numbers and manufacturers		K091305 EasyGlide	K092429 Byrne Medical	K103239 US Endoscopy
Device	ClearPath Tubing	ClearPath Tubing	Endogator Tubing	Velocity system
Class	Class II	Class II	Class II	Class II
Product code	OCX	FDF	KOG	OCX
CFR	876.1500	876.1500	876.1500	876.1500
Design	Tube connecting the water source through the peristaltic pump to the irrigation device. Check valve prevents backflow.	Tube connecting the water source through the peristaltic pump to the irrigation device.	Tube connecting the water source through the peristaltic pump to the irrigation device. Check valve prevents backflow.	Tube connecting the water source to the irrigation device via a manual foot pump.
Indications for use	The ClearPath Tubing is intended to provide irrigation via irrigation fluids, such as water, during gastrointestinal endoscopic procedures when used in conjunction with the ClearPath irrigation system components (ClearPath Lower GI, ClearPath Upper GI, and ClearPath Irrigator).	The ClearPath is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water) and feces. It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.	The EndoGator ™ system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The Irrigation System (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via irrigation fluids, such as sterile water, during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.
Environment of Use	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.
Prescriptive	Yes, only trained medical personnel	Yes, only trained medical personnel	Yes, only trained medical personnel	Yes, only trained medical personnel
Principle of operation	Tubing passing through a peristaltic pump	Tubing passing through a peristaltic pump	Tubing passing through a peristaltic pump	Tubing connecting to a manual foot pump
Single use	Yes	Yes	Yes	Yes
Packaged Sterile	No	No	Yes	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2012

EasyGlide Ltd.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K112318
Trade/Device Name: ClearPath Tubing
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: June 17, 2012
Received: June 19, 2012

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K112318

Device Name: ClearPath Tubing

Indications for Use:

The ClearPath Tubing is intended to provide irrigation via irrigation fluids, such as water, during gastrointestinal endoscopic procedures when used in conjunction with the ClearPath irrigation system components (ClearPath Lower GI, ClearPath Upper GI, and ClearPath Irrigator).

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112318